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Patent
Attorney's Docket No. 033053-034

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	)	
Mark A. GALLOP et al.	)	
Application No.: 09/972,402	)	Group Art Unit: 1654
Filed: October 5, 2001	)	Examiner: Michael V. Meller
For: COMPOUNDS FOR SUSTANIED RELEASE OF ORALLY DELIVERED DRUGS	)	Confirmation No.: 3864

RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner of Patents and Trademarks
Washington, D.C. 20231

re-do election w/ mavis's suggested form H

Sir:

In complete response to the Office Action of May 20, 2003, Applicants submit the following response.

In the Office Action, the Examiner sets forth a restriction requirement among six groups of claims:

I. Claims 1 and 7-24, drawn to a first method of using a compound, classified in class 424.
II. Claim 2, drawn to a first compound, classified in class 514.
III. Claim 3, drawn to a pharmaceutical composition, classified in class 436.
IV. Claims 4 and 25-42, drawn to a second method of using a compound, classified in class 530.
V. Claim 5, drawn to a third compound, classified in class 930.
VI. Claim 6, drawn to a pharmaceutical composition comprising a compound, classified in class 435.

Applicants respectfully traverse the restriction requirement as set forth in the Office Action. Applicants respectfully assert that the inventions of Group II, III, V, and VI should properly be examined together. Groups II and III are directed to compounds and Groups V and VI are directed to pharmaceutical compositions comprising the compounds of Groups II and III, respectively.

Group II (claim 2) is directed to a generic compound of formula (I):

D-Y-T (I)

wherein Y is selected such that a portion of the linker is cleaved to release drug D or active metabolite thereof during each cycle through the enterohepatic circulation whereupon *sustained release of drug D* in said animal is achieved.

Group V (claim 5) is also directed to a generic compound of formula (I):

D-Y-T (I)

wherein Y is selected to provide for *sustained release* of drug D in said animal *for a period of at least 10% longer* than the oral delivery of drug D itself. Accordingly, both the compounds of Groups II and V provide for sustained release of drug D. Claim 5 is more specific in providing that the period of sustained release be at least 10% longer than the oral delivery of drug D itself. As described above, Groups V and VI are directed to pharmaceutical compositions comprising the compounds of Groups II and III, respectively, as described above. The pharmaceutical compositions comprise an effective amount of the compounds of Groups II and III respectively and a pharmaceutically acceptable diluent. Accordingly, the inventions of Groups II, III, V, and VI are closely related and as such, should be examined together.

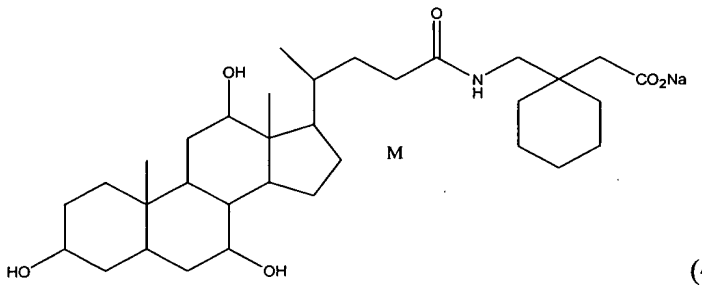
Applicants further note that the inventions of Groups II, III, V, and VI are so closely related and that a proper search of any of the claims should, by necessity, require a proper search of the others. Thus, Applicants submit that all of the claims can be searched simultaneously, and that a duplicative search, with possibly inconsistent results, may occur if the restriction requirement is maintained.

Applicants submit that any nominal burden placed upon the Examiner to search accordingly to determine the art relevant to Applicants' overall invention is significantly outweighed by the public's interest in not having to obtain and study many separate patents in order to have available all of the issued patent claims covering Applicants' invention. The alternative is to proceed with the filing of multiple applications, each consisting of generally the same disclosure, and each being subjected to essentially the same search, perhaps by different Examiners on different occasions. This process would place an unnecessary burden on both the Patent and Trademark Office and on the Applicants.

Regardless of whether the two inventions are independent or distinct, Applicants respectfully assert that the Examiner need not have restricted the application. MPEP § 803 requires that "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." Therefore, it is not mandatory to make a restriction requirement in all situations where it would be deemed proper.

In the interest of economy, for the Office, for the public-at-large, and for Applicants, reconsideration and withdrawal of the restriction requirement are requested.

Nevertheless, to comply with the requirements of 37 C.F.R. § 1.143, Applicants provisionally elect, with traverse, to prosecute the invention of Group II (claim 2), for prosecution in the above-identified application. As required under 35 U.S.C. § 121, Applicants were further required to elect a single disclosed species. Accordingly, Applicants elect, with traverse, the compound of formula I as illustrated in Figure 10 compound (4):



(4)

It is believed that claims 2, 3, 5, and 6 are readable upon the elected species as defined above. Applicants have no intention of abandoning any non-elected subject matter and expressly reserve the right to file one or more continuation and/or divisional applications directed to the non-elected subject matter.

The Examiner is invited to contact the undersigned at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

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By M. M. Hayworth
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Dated: JUN 20, 2003

Attorney Docket Patent 033053-034

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Mark A. GALLOP et al. Group Art Unit: 1654

Application No.: 09/972,402 Examiner: Michael V. Meller

Filing Date: October 5, 2001 Confirmation No.: 3864

Title: COMPOUNDS FOR SUSTAINED RELEASE OF ORALLY DELIVERED DRUGS

AMENDMENT/REPLY TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Enclosed is a reply for the above-identified patent application.

☐ A Petition for Extension of Time is also enclosed.

☐ Terminal Disclaimer(s) and the ☐ $55.00 (2814) ☐ $110.00 (1814) ee per Disclaimer due under 37 C.F.R. § 1.20(d) are also enclosed.

☐ Also enclosed is/are .

☐ Small entity status is hereby claimed.

☐ Applicant(s) requests continued examination under 37 C.F.R. § 1.114 and enclose the ☐ $375.00 (2801) ☐ $750.00 (1801) fe e due under 37 C.F.R. § 1.17(e).

☐ Applicant(s) previously submitted _____ on _____ for which continued examination is requested.

☐ Applicant(s) requests suspension of action by the Office until at least _____, which does not exceed three months from the filing of this RCE, in accordance with 37 C.F.R. § 1.103(c). The required fee under 37 C.F.R. § 1.17(i) is enclosed.

☐ A Request for Entry and Consideration of Submission under 37 C.F.R. § 1.129(a) (1809/2809) is also enclosed.

☒ No additional claim fee is required.

☐ Charge _____ to Deposit Account No. 02-4800.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17, 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

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Date: June 20, 2003

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